

REMARKS

Applicants are seeking to make two amendments to this application.

A. The Section 120 Specific Reference

First, pursuant to 35 U.S.C. § 120, Applicants are adding a specific reference to application Serial No. 06/643,306 ("the '306 application"). The '306 application describes the cloning of HTLV-III from an immortalized human T-cell line, and preparation of a HTLV-III clone used in the '339 application. The '306 application was filed by two inventors common to this application, Drs. Gallo and Wong-Staal, and was co-pending with this application.<sup>1</sup> The '306 application was subsequently re-filed as a continuation application, Serial No. 07/033,891, filed April 3, 1987, now abandoned; continuation-in-part application Serial No. 07/160,827, filed February 26, 1988, now abandoned; continuation application Serial No. 07/832,603, filed February 12, 1992, now

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<sup>1</sup> As filed, the '339 application listed Dr. Nancy Chang as the sole inventor. On May 14, 1986 petitions to change the inventorship to add Dr. Robert Gallo and Dr. Flossie Wong-Staal were filed in the '339 application and in U.S.S.N. 06/693,866, the continuation in part application filed on January 23, 1985. Apparently, the '339 application was abandoned before the petition to change inventorship was acted upon. However, in Paper No. 13, issued November 27, 1987, the PTO examiner changed the inventorship of the '866 application to include Drs. Gallo and Wong-Staal. Pursuant to the Weil v. Fritz, 572 F.2d 856 (C.C.P.A. 1978) and In re Schmidt, 293 F.2d 274 (C.C.P.A. 1961) decisions, amendment of the '866 application was legally effective to change the inventorship of the '339 application. Thus, Drs. Chang, Gallo and Wong-Staal are the legal inventors of the '339 application.

abandoned and currently pending continuation application, Serial No. 08/385,231, filed February 8, 1995, (collectively "the '306 family of applications").

The law is well developed that an abandoned application can be amended to add a specific reference under 35 U.S.C. § 120. Sampson v. Commissioner of Patents, 195 U.S.P.Q. 136 (D.C. D.C. 1976). Thus, the amendment of this application to add the specific reference under section 120 is appropriate.

B. The Deposit Reference

The second amendment is the insertion of a reference to the pre-filing date deposit of a molecular clone of HTLV-III referred to in the specification. This deposit, accepted by the ATCC on July 30, 1984, is also referenced in the '306 application and the '306 family of applications. Pursuant to the authority of In Re Lundak, 773 F.2d 1216 (Fed. Cir. 1985), the reference to the deposit is appropriate.

Specific reference to the deposited clone is found at the following locations in the application:

The '339 application describes the "cloning of HTLV-III DNA in recombinant/vector host systems capable of expressing immunoreactive HTLV-III polypeptides" (p.3, 28-30).

The '339 application discusses as an embodiment of the invention that "lambda<sub>10</sub> clones harboring HTLV-III DNA are cloned from the replicated form of the virus" (p. 8, 33 to p. 9, 1). In the '339 application as originally filed, the nomenclature "lambda

<sub>10</sub> clones" refers to the recombinant phage clone BH10. The nomenclature designates the HTLV-III molecular clone BH10 inserted into bacteriophage lambda, which was used in expression of HTLV-III polypeptides and expression screening. As used in the '339 application, "lambda<sub>10</sub> clones" represents an abbreviated or shorthand nomenclature for lambda BH10 or  $\lambda$ BH10 recombinant phage clones harboring HTLV-III DNA of the molecular clone BH10 in bacteriophage lambda (See attached Chang Exhibit 13, B.H. Hahn et al., 1984, Nature, 312:166-169, p.167 and Figure 2).

The '339 application also describes the characteristics of the lambda BH10 clone, designated " $\lambda_{10}$ " in Figs. 1a and 1b, at p. 9, 3-8:

Cuts are made in the cloned HTLV-III DNA with the restriction enzyme SstI. (Figure 1a) Because there are two SstI recognition sites within the LTR of HTLV-III DNA, one LTR region is not present in the cloned DNA sequence removed from the lambda<sub>10</sub> vector...

For HTLV-III protein expression, the phage lambda gt11 is used as described and taught in the '339 specification at p. 12, 1-5 and 11-14: "The EcoRI linker ligated [HTLV-III] DNA is then treated with EcoRI... and cloned in an expression vector, [ $\lambda$ ]gt11". (p. 12, 1-5). In addition, it is disclosed that "AIDS patient serum was used to probe the gt11 library of HTLV-III genomic DNA..." (p. 12, 11-14).

The restriction maps presented in Figs. 1a, 1b, and 2 of the '339 application show restriction enzyme sites in the genome of molecularly cloned HTLV-III which correspond to the genomic restriction enzyme map of clone BH10 depicted in Fig. 2 of the '306 family of applications.

Further, inventor Nancy Chang attested to the fact that bacteriophage lambda containing HTLV-III DNA of the genomic clone BH10 (i.e., lambda BH10 or  $\lambda_{BH10}$ ) was used in the HTLV-III cloning and expression work described in the '339 application (See attached Chang Affidavit Exhibit 2, Declaration of Nancy T. Chang, dated February 23, 1986, which accompanied the Petition to Correct Inventorship, filed May 14, 1986 in the '339 application of Chang et al.). In this Declaration, Chang stated that

[t]he experimental work described in the application began at Centocor upon receipt of genomic HTLV-III DNA from the laboratories of Dr. Gallo and Dr. Wong-Staal. Dr. Gallo and Dr. Wong-Staal supplied a recombinant phage (designated  $\lambda_{BH10}$ ) consisting of the genomic HTLV-III cDNA recombined with a phage vector. The HTLV-III cDNA insert was excised from  $\lambda_{BH10}$  and fragmented[,] and the subgenomic fragments were cloned and expressed in host cell systems as described in the application.

(Chang Affidavit Exhibit 2, Chang Declaration, p. 2, ¶4). This statement is supported by the '339 application disclosure at p. 8, 32-33 to p. 9, 1-8.

The ATCC deposit receipt for recombinant clone λBH10, received on July 30, 1984 is submitted as Chang Documentary Exhibit 12. The receipt establishes full compliance with the depository rules of the Patent Office.

Since the '339 application is abandoned, applicants have submitted herewith a petition under Rule 1.182 for entry of the amendments.

CONCLUSION

Entry of the amendments is requested.

Respectfully submitted,

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**CERTIFICATE OF MAILING**

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail in an envelope addressed to: the Assistant Commissioner for Patents, Washington, D.C., 20231, on February 20, 1996.

Dated: February 20, 1996

By:

Eugene Moroz



A handwritten signature in black ink, appearing to read "Eugene Moroz", is written over a horizontal line. The signature is fluid and cursive, with a large, stylized 'E' at the beginning.